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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,600	04/03/2007	Patrick Leahy	3994942	8346

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COLUMBUS, OH 43215

EXAMINER
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BOOTH, MICHAEL JOHN

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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09/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/596,600

**Applicant(s)**

LEAHY, PATRICK

**Examiner**

MICHAEL J. BOOTH

**Art Unit**

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 05/05/2009 have been fully considered but they are not persuasive. Examiner carefully reviewed applicant arguments; however, the examiner respectfully disagrees. With specific regards to arguments on pages 5 and 6, the claim language as written uses broad terms that are open to broad interpretation, for example, the limitation "substantially". Further, applicant continues to argue functional language whereby the art only requires to possess the capability (or to be adapted to enable the device to be secured to the stomach wall) to perform such function, and it is the examiners interpretation that it does possess that capability. Thus, examiner must maintain previous rejection set forth.

### ***Election/Restrictions***

Claims 18-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/05/2009.

Applicant's election without traverse of group I with respect to claims 1-17 in the reply filed on 05/05/2009 is acknowledged.

### ***Status of the Claims***

The amendment filed 05/05/2009 hereby identifies the claims as follows:

*Claims 1-4 and 6-17 are pending and stand rejected below.*

*Claims 5 and 18-24 are cancelled by applicant.*

## **DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claims 1-3, 6-12 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kilcoyne et al USPN 6,264,700 "Kilcoyne".***

***With respect to claims 1-3, 6-8, 9-12;*** Kilcoyne discloses a valve (20) that permits unidirectional flow and allows reverse flow when a pressure meets a certain threshold. (column 7, lines 18-26 and 40-56). The valve comprises a retention means (namely an anchor, 18) which secures the valve into a wall. The material used allows the valve to be flexible and collapsible (column 2, lines 39-48) and is biodegradable. Kilcoyne discloses a retention means, or more specifically a flange (namely an anchor, 18, which qualifies as a flange, which is a retention means) where the flange may contain an adhesive. (column 4, lines 16-32). Further, the flange defines a conduit, where the flange comprises apertures (38). The valve is to be positioned with the retention members against the wall (abstract) and is distensible due to the material used and is adapted to be clamped to the wall. The term "substantially" is interpreted broadly and it is the examiners position that the claim limitation is met, as broadly interpreted. The flange is disposed "substantially" circumferentially about the valve, and adapted to enable the device to be secured to the stomach wall, as it possesses the capability of performing the function.

**With respect to claims 15-17;** Kilcoyne discloses the claim limitations as claimed above; further, a dispensing or insertion means (namely a tubular introducer) which is an elongated tube adapted to receive and dispense or insert the device into the stomach. (column 10, lines 3-25).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

***Claims 4 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne as applied to claims 1, 11, and 12 above, and further in view of Taylor USPN 6,254,642.***

**With respect to claim 4;** Kilcoyne discloses the invention substantially as claimed. However, Kilcoyne does not disclose a mitral valve. Taylor discloses a mitral valve (column 6, lines 20-39) for the purpose of easier implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify Kilcoyne's valve with the teachings of Taylor with respect to the mitral valve in order to allow for easier implantation.

***With respect to claims 13-14;*** Kilcoyne discloses the invention substantially as claimed. However, Kilcoyne does not disclose a tether detachably engageable with the distensible element to allow the element to be drawn against the stomach, further with an inflatable balloon. Taylor discloses an inflatable balloon to allow the element to be drawn against the stomach wall (column 2 & 3) for the purpose of allowing the retention members (namely the anchors) engage with the wall during implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kilcoyne with an inflatable balloon in order to engage the retention members with the wall during implantation.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. BOOTH whose telephone number is (571)270-7027. The examiner can normally be reached on Monday thru Thursday 8:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. B./  
Examiner, Art Unit 3774  
August 31, 2009

/William H. Matthews/  
Primary Examiner, Art Unit 3774